

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of:	)	
	)	
Hans-Peter HAUSER et al.	)	Group Art Unit: Not Assigned
	)	
Application No.: Not Yet Assigned	)	Examiner: Not Assigned
	)	
Filed: Herewith	)	
	)	
For: MODIFIED cDNA FACTOR VIII	)	
AND ITS DERIVATIVES	)	

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

**INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.97(b)**

Pursuant to 37 C.F.R. §§ 1.56 and 1.97(b), Applicants bring to the attention of the Examiner the documents listed on the attached PTO 1449. This Information Disclosure Statement is being filed concurrently herewith this application.

Copies of the listed documents, including any copending patent applications, are attached.

Applicants respectfully request that the Examiner consider the listed documents and indicate that they were considered by making appropriate notations on the attached form.

An English language counterpart to EP 0 303 540 has been provided as U.S. Patent No. 5,112,950. An English language abstract of EP 0 295 597 has also been provided.

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This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that each or all of the listed documents are material or constitute "prior art." If the Examiner applies any of the documents as prior art against any claim in the application and Applicants determine that the cited documents do not constitute "prior art" under United States law, Applicants reserve the right to present to the Office the relevant facts and law regarding the appropriate status of such documents.


Applicants further reserve the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

If there is any fee due in connection with the filing of this Statement, please charge the fee to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,  
GARRETT & DUNNER, L.L.P.

Dated: November 25, 2003

By:   
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## INFORMATION DISCLOSURE CITATION

Atty. Docket No.	06478.1496	Appln. No.	Not Assigned
Applicant	Hans-Peter HAUSER et al.		
Filing Date	Herewith	Group:	Not Assigned

## U.S. PATENT DOCUMENTS

Examiner Initial*		Document Number	Issue Date	Name	Class	Sub Class	Filing Date If Appropriate
	A	5,112,950	5/12/92	Meulien et al.	530	383	
	B	5,663,060	9/02/97	Lollar et al.	435	69.6	
	C	App. No. 09/150,811	Publication Date: 5/30/02	Connelly et al.	435	69.1	

## FOREIGN PATENT DOCUMENTS

		Document Number	Publication Date	Country	Class	Sub Class	Translation Yes or No
	D	0 197 901	10/15/86	Europe			
	E	WO 87/04187	7/16/87	WIPO			
	F	WO 88/00831	2/11/88	WIPO			
	G	0 295 597	12/21/88	Europe			No; See Derwent Abstract
	H	0 303 540 B1	2/15/89	Europe			No; See Ref. A
	I	WO 95/18827	7/13/95	WIPO			
	J	WO 00/71714	11/30/00	WIPO			

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

	Andersson et al., "Isolation and Characterization of Human Factor VIII: Molecular Forms in Commercial Factor VIII Concentrate, Cryoprecipitate, and Plasma," <i>Proc. Natl. Acad. Sci. USA</i> , 83: 2979-2983 (1986).
	Brinkhous et al., "Purified Human Factor VIII Procoagulant Protein: Comparative Hemostatic Response After Infusions into Hemophilic and von Willebrand Disease Dogs," <i>Proc. Natl. Acad. Sci. USA</i> , 82:8752-8756 (1985).
	Eaton et al., "Construction and Characterization of an Active Factor VIII Variant Lacking the Central One-Third of the Molecule," <i>Biochemistry</i> , 25:8343-8347 (1986).
	Fay et al., "Characterization of the Interaction Between the A2 Subunit and A1/A3-C1-C2 Dimer in Human Factor VIII <sub>a</sub> ," <i>J. Biol. Chem.</i> , 267:13246-13250 (1992).
	Fay et al., "Human Factor VIII <sub>a</sub> Subunit Structure: Reconstitution of Factor VIII <sub>a</sub> From The Isolated A1/A3-C1-C2 Dimer and A2 Subunit," <i>J. Biol. Chem.</i> , 266:8957-8962 (1991).

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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)	
	Langner et al., "Synthesis of Biologically Active Deletion Mutants of Human Factor VIII:C," <i>Behring Inst. Mitt.</i> , 82:16-25 (1988).
	Lollar et al., "Coagulant Properties of Hybrid Human/Porcine Factor VIII Molecules," <i>J. Biol. Chem.</i> , 267:23652-23657 (1992).
	Meulien et al., "A New Recombinant Procoagulant Protein Derived from the cDNA Encoding Human Factor VIII," <i>Protein Engineering</i> , 2:301-306 (1988).
	Persson et al., "Kinetics of the Interaction Between the Human Factor VIIIa Subunits: Effects of pH, Ionic Strength, Ca <sup>2+</sup> Concentration, Heparin, and Activated Protein C-Catalyzed Proteolysis," <i>Biochemistry</i> , 34:12775-12781 (1995).
	Pipe et al., "Characterization of a Genetically Engineered Inactivation-Resistant Coagulation Factor VIIIa," <i>Proc. Natl. Acad. Sci. USA</i> , 94:11851-11856 (1997).
	Plantier et al., "A Factor VIII Minigene Comprising the Truncated Intron I of Factor IX Highly Improves the <i>In Vitro</i> Production of Factor VIII," <i>Thromb. Haemost.</i> , 86:596-603 (2001).
	Saenko et al., "Molecular Defects in Coagulation Factor VIII and Their Impact on Factor VIII Function," <i>Vox Sanguinis</i> , 83:89-96 (2002).
	Sarver et al., "Stable Expression of Recombinant Factor VIII Molecules Using a Bovine Papillomavirus Vector," <i>DNA</i> , 6:553-564 (1987).
	Toole et al., "A Large Region (≈95 kDa) of Human Factor VIII is Dispensable for <i>In Vitro</i> Procoagulant Activity," <i>Proc. Natl. Acad. Sci. USA</i> , 83:5939-5942 (1986).
	Vehar et al., "Structure of Human Factor VIII," <i>Nature</i> , 312:337-342 (1984).
	Wood et al., "Expression of Active Human Factor VIII From Recombinant DNA Clones," <i>Nature</i> , 312:330-337 (1984).
	Derwent Abstract for EP 0 295 597 (Ref. G).

Examiner	Date Considered
*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	
Form PTO 1449	Patent and Trademark Office - U.S. Department of Commerce

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